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Guidance for the Reregistration of Pesticide Products Containing Phosalone as the Active Ingredient

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EPA

Guidance for the Reregistration of Pesticide Products Containing PHOSALONE as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

PHOSALONE

097701

AS THE ACTIVE INGREDIENT

CASE NUMBER 27

CAS NO. 2310-17-0

November, 1987

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

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This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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I. INTRODUCTION

This document is a revised Registration Standard for the subject chemical. In its original Standard, the Agency described the available data supporting the registration of the chemical and its assessment of those data in terms of whether the pesticide met the "no unreasonable adverse effects" standard of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The Agency concluded that additional data were necessary to fully evaluate the pesticide and, in issuing the Standard, required that registrants supply those data. The Agency also set out label requirements needed to ensure that products containing the pesticide were labeled adequately to protect public health and the environment.

The Agency has now received and reviewed the new data and has updated and revised its scientific and regulatory conclusions concerning the pesticide. The Registration Standard contains the Agency's updated scientific assessment of this pesticide and its currently registered uses. As part of its review, the Agency has reassessed current tolerances for the pesticide and has determined whether they are adequate. The tolerance reassessment is included in this Registration Standard. The Agency's scientific assessment is set out in Section III of this Standard. EPA's regulatory conclusions are set out in Section IV.

In the intervening period, the Agency has expanded its data requirements, and adopted more stringent standards for data acceptability. Rereview of some studies considered acceptable at the time of issuance of the original Standard reveals that the studies do not meet current standards. Thus additional data requirements are identified in the data tables in Appendix I.

Based upon the new data, the Agency has also reviewed the labeling requirements for this pesticide chemical. New label requirements are set out in Section IV.D., together with the schedule for accomplishing label revisions.

Each registrant who wishes to continue to sell and distribute a product containing this pesticide must bring his product into compliance with FIFRA, as instructed in this revised Registration Standard.

Detailed scientific reviews are not contained in this document, but are available upon request[1]. These reviews focus upon the pesticide active ingredient. The scientific reviews primarily discuss the Agency's evaluations of data in its files which pertain to the active ingredient. These reviews also discuss potential hazards that may be associated with the end-use products that contain the active ingredient. EPA will apply the provisions of this Registration Standard to end-use products as necessary to protect man and the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

In Registration Standard documents, the Agency generally prescribes steps for registrants to take to maintain their registrations in compliance with FIFRA. Depending upon the regulatory position, these steps may include:

1. Submission of data in support of product registration;

2. Modifications of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of the uses or formulation types; or

6. Specification of packaging limitations.

If the registrants fail to comply with these requirements, EPA may issue a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data) the pesticide registration(s).

If hazards to man or the environment are identified, the Agency may initiate a special review, in accordance with 40 CFR Part 154, to examine in depth the risks and benefits of use of the active ingredient. If the Agency determines that the risks of the pesticide's use outweigh its benefits, EPA will propose additional regulatory actions, such as cancellation of the uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions to FIFRA sec. 3(c)(2)(B) to require registrants to submit data concerning the chemical, toxicological, and environmental characteristics and fate of a pesticide. This document identifies data requirements that EPA believes to be necessary to resolve its concerns about Phosalone. These requirements are listed in the Tables A, B, and C in Appendix I. If any registrants fail to comply with the DCI requirements enumerated in this Registration Standard, EPA may issue a Notice of Intent to Suspend the affected product registrations.

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- EPA Form 8580-4 Product Specific Data Report
- EPA Form 8570-27 Generic Data Exemption Statement

FIFRA sec. 6(a)(2) requires registrants to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information concerning the pesticide, including interim or preliminary results of studies, suggesting possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of chemical

The following pesticide chemical is covered by this revised Registration Standard:

Common name: Phosalone (ANSI)

Chemical name (IUPAC): S-6-chloro-2,3-dihydro-2-oxobenzoxazol-3-yl methyl 0,0-diethyl phosphorodithioate

Alternate Chemical Names: S-[(6-chloro-2-oxo-3(2H)benzoxazolyl)methyl] 0,0-diethylphosphorodithioate; 0,0-diethylphosphorodithioate S ester with 6-chloro-3-(mercaptomethyl)-2-benzoxazolinone; 0-0-diethyl-S-[(6-chloro-2-oxobenzoxazolin-3-yl)methyl]phosphorodithioate; S-[6-chloro-3-(mercaptomethyl)-2-benzoxazolinone] 0,0-diethylphosphorodithioate; 0,0-diethyl-S-[6-chloro-3-(mercaptomethyl)-2-benzoxazolinone] phosphorodithioate.

CAS Number: 2310-17-0

OPP (Shaughnessy) Number: 097701

Empirical Formula: $C_{12}H_{15}ClNO_4PS_2$

Trade names: Azontene; Benzofos; RP11974; Rubitox; and Zolone

Physical Characteristics of Chemical:

Technical Phosalone
Color: White
Physical State: Crystalline solid
Molecular Weight: 367.8
Melting Point: 45-75°C
Solubility: At 20°C: 1.7 ppm in water; 20 g/100 ml in methanol and ethanol; and 10 g/100 ml in acetone, benzene, cyclohexanone, acetonitrile, xylene, toluene, dioxane, chloroform, and methyl chloride.
Vapor Pressure: $\leq 0.5 \times 10^{-6}$ mmHg at 24°C and 16.4×10^{-6} at 60°C
Density: 1.391 g/ml at 20°C

B. Use Profile

Type of Pesticide: Insecticide and acaricide.

Pests Controlled: Insects and mites

Registered Uses: Phosalone is registered on a variety of orchard crops, vegetables, roses, and arborvitae.

Predominant Uses: Pecans and walnuts

Mode of Activity: Inhibits the enzyme acetyl cholinesterase

Method of Application: Foliar: ground, and aircraft.

Formulations:
94% Technical
25% Wettable Powder
34.4% (3lb/gal) Emulsifiable Concentrate
17.2% (1.35lb/gal) Emulsifiable Concentrate

Basic Registrant: Rhone-Poulenc, Inc.

Number of Registrants: 3

End-Use Registrations:

Formulation	Section 3	Section 24C	Intrastate
Wettable Powder	1	-	16
Emulsifiable Concentrate	3	1	5

Phosalone is registered for use on almonds, apricots, apples, artichokes, cherries, grapefruit, lemons, oranges, walnuts, grapes, nectarines, peaches, filberts, pears, pecans, plums, prunes, potatoes, roses, and arborvitae.

About 80 percent of the phosalone used annually in the U.S. is used on pecans. The 580-690 thousand base acres of pecans treated each year represents 80 to 90 percent of the total U.S. pecan acreage. About 4 or 5 applications are made each year, with the amount of active ingredient used per application ranging from about 1/2 to 2 pounds active ingredient per acre. An estimated 2.6 to 3.6 millon acre treatments are made each year.

The use of phosalone on apples, grapes, walnuts, cherries, and pears accounts for a large part of the remaining 20 percent of the annual phosalone usage in the U.S.

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has reviewed all data currently supporting the registration of phosalone and has concluded that numerous data gaps exist. Based on the available data, EPA has reached the following conclusions. The points summarized below are presented in further detail, in the context of EPA's science findings and additional data requirements, in Sections B through D.

1. Technical phosalone is a moderately acute toxic pesticide for oral and dermal routes of exposure, Toxicity Category II.

2. Phosalone may have an adverse impact on birds and aquatic organisms resulting from all use patterns except ornamentals. Aquatic and terrestial field studies are required to determine the potential risks to these organisms. Restricted Use labeling is required on an interim basis due to aquatic toxicity and avian hazards.

3. Available laboratory data show that technical phosalone is very highly toxic to fish and aquatic invertebrates.

4. Preliminary data indicate that groundwater contamination resulting from phosalone applications is unlikely, but the Agency is unable to conduct a complete assessment due to data gaps.

5. Phosalone meets the toxicity and exposure criteria defined under the Pesticide Assessment Guidelines, Subdivision K, for reentry. The Agency will retain the current 24 hour reentry interval based on epidemiological and current agriculture uses.

The Agency has identified the data it believes are necessary to fully evaluate the human and environmental risks associated with the use of phosalone. These data must be submitted in order to maintain registration of products or to register new products containing phosalone. A summary of these data gaps appears in Figure I. Please note that this is only a summary and complete details can be obtained by referring to the tables in Appendix I.

The Agency has also determined that certain label restrictions and revisions are necessary. Refer to Section VI.D for a description of the required revisions.

FIGURE 1 -DATA GAP TABLE

TOXICOLOGY

Primary Eye Irritation
Dermal Sensitization
Acute Inhalation
Subchronic
Mutagenicity
Teratology
2-Generation Reproduction
Dermal Absorption
General Metabolism
Oncogenicity

ENVIRONMENTAL FATE

Aged Leaching Study
Foliar Dissipation
Rotational Crop (Confined)
Spray Drift
Soil Dissipation

ECOL

RESIDUE CHEMISTRY

Animal Metabolism
Plant Metabolism
Storage Stability
Residue Studies

PRODUCT CHEM

Product Chemistry

B. TOXICOLOGICAL ASSESSMENT

1. MANUFACTURING FORMULATION

Acute Toxicity

a. Acute oral LD50

Technical phosalone was administered in single oral doses of 83, 100, 124, 150, 186, or 225 mg/kg. Signs of toxicity included salivation, lacrimation, muscle fasciculation, convulsions, and respiratory dysfunction which preceded death. The LD50 for male rats is 125 mg/kg (102-152) and for female rats is 90 mg/kg (68-119). Based on this study the product was classified as moderately toxic and placed in Toxicity Category II for this route of exposure.

b. Acute dermal LD50

Technical phosalone was applied as an oil and alcohol solution to depilated areas of skin to groups of rabbits and rats. Rabbits were given 0.5 or 1.0 gm/kg, while rats received 100, 200, 600, or 800 mg/kg of phosalone. Signs of toxicity were characteristic of cholinesterase inhibition as described for acute oral toxicity. Deaths occurred within four days. Dermal LD50's were: for rabbits > 1000 mg/kg and for rats >390 mg/kg. These data demonstrate that technical phosalone has a high degree of acute dermal toxicity, placing phosalone in Toxicity Category II.

c. Acute inhalation LC50

Acute inhalation study requirements for the technical material have been waived. The physical form of the technical material is a waxy solid. Particle size data indicates that 93% of the particles analyzed were greater than 100 microns. Particles less than 15 microns are considered to be within the respirable range.

d. Neurotoxicity

Technical phosalone did not produce organophosphate type delayed neurotoxicity in an acute delayed neurotoxicity study in hens.

e. Dermal irritation

Primary dermal irritation data demonstrate that technical phosalone is a mild skin irritant, placing phosalone in Toxicity Category IV.

No primary eye irritation or dermal sensitization study is available. These studies are required for the technical material.

Subchronic Toxicity

No acceptable subchronic rat study is available; however, an adequate chronic feeding study in the rat is available and was used to evaluate subchronic toxicity in the rat.

A partially acceptable subchronic study in dogs is available. Groups of dogs were fed diets containing 0, 10, or 25 ppm phosalone for 6 months, at which time two animals per sex were sacrificed and the remainder placed on phosalone-free diets for a further 4 weeks before being sacrificed. No effects on body weights, food consumption, clinical signs of cholinesterase inhibition, hematological parameters, or gross or microscopic examinations were observed. The only effects noted were depressions of plasma cholinesterase. Although actual compound intakes were not calculated, these dietary levels corresponded to approximately 0.25 and 0.625 mg/kg/day, respectively.

A subchronic feeding study is required in the dog to determine a NOEL (no-observed-effect level) for cholinesterase inhibition due to phosalone.

In a 21-day subchronic dermal exposure study, groups of New Zealand rabbits were treated for 3 weeks with concentrations of technical phosalone providing 0.4, 2.0 and 10 mg/kg/day applied to both intact and abraded dorsal skin sites. Cholinesterase activity was decreased in treated females. Both plasma and red blood cell values were variable, and the only consistent doserelated depression recorded was in brain values for the high-dose females. The NOEL for this study was 2.0 mg/kg/day based upon brain cholinesterase inhibition of 10 mg/kg/day in female rabbits.

Chronic Toxicity

In an acceptable two year feeding study, groups of rats (30 per sex) were given diets containing 0, 25, 50 or 250 ppm phosalone. A NOEL of 25 ppm was established in this study based upon inhibition of erythrocyte cholinesterase at 50 and 250 ppm.

In a 2 year feeding study, groups of beagle dogs (four per sex) were given diets containing 0, 100, 200, or 1000 ppm phosalone. At the highest dose, effects noted were inhibition of red blood cell and brain cholinesterase activity, decreased body weight, hypersensitivity, and generalized muscular fasciculations. A NOEL was not established due to a reduction in plasma cholinesterase values at the lowest dietary level, 100 ppm.

Although requirements for chronic data have been minimally satisfied in the dog, additional data must be submitted to establish definitive no-effect-levels for cholinesterase inhibition in plasma, erythrocyte and tissues (preferably brain).

This requirement can be satisfied by a subchronic dog study.

Oncogenicity

The rat chronic study previously described above fails to adequately assess the oncogenicity of phosalone. The number of test animals used was insufficient to evaluate the sensitivity of the assay.

A rat oncogenicity study is required.

A 104-week feeding oncogenicity study in CD-1 mice was reviewed and found to be partially acceptable. Fifty animals per sex were used. The dietary doses given were 0, 5, 50, and 100 ppm. Female mice demonstrated an increased incidence of leiomyomas and leiomyosarcomas of the uterus and of the Harderian gland adenomas.

Historical control data must be submitted for these tumor types in female CD-1 mice. Upon receipt of these data, the Agency will reevaluate this study.

Reproduction and Teratology Effects

Reproduction

An available three-generation reproduction study was reviewed and found to be unacceptable because of serious deficiencies. Specifically, there was no indication of minimal toxicity at the highest dose and no rationale for dose selection. Only two doses were tested, 25 and 50 ppm, whereas at least three doses are currently considered acceptable. At the lowest dose, no effects were noted.

A two-generation reproduction study in the rat is required.

Teratology

An available rabbit teratogenicity study was reviewed and found to be unacceptable. Groups of 25 pregnant rabbits received a daily oral gavage dose of 0, 2, 6, or 18 mg/kg for 10 days during gestation. At no dose of phosalone administered were there any maternal toxic effects noted, nor any evidence of induced fetotoxicity or developmental defects in contrast to the postive control, thalidomide. Also lacking was any evidence that a dose sufficiently high enough to affect clinical, reproductive, or fetal parameters was used.

No data are available to assess teratological effects in rats.

Teratology studies in both the rat and rabbit are required.

Mutagenicity

Gene Mutation

A bacterial assay for reverse gene mutation with technical phosalone was conducted using Salmonella typhimurium strains. This study was unacceptable because positive controls were not run concurrently with test strains.

Chromosomal Aberrations

A dominant lethal study was conducted in mice. Five groups of ten males each were given a single dose of 0, 10, 30, or 75 mg/kg phosalone by gavage or an intraperitoneal dose of 40 mg/kg of cyclophosphamide (reference mutagen). This study was unacceptable because no indication was given that the highest dose tested produced any clinical or reproductive effects.

In view of the unacceptable mutagenicity assays described above, the Agency is requiring the full minimum battery of mutagenicity assays with phosalone be submitted, consisting of;

1. A mammalian in vitro point mutation test
2. A mammalian in vitro cytogenetics test
3. At least one test for DNA damage/repair

Metabolism

No valid metabolism study is available. This study is required.

Dermal Absorption

A dermal absorption study was reviewed and found to be unacceptable. Radiolabeled phosalone, 13.9 mg, was applied to the skin of a pig. Results of this study indicated that phosalone does not appear to be absorbed percutaneously; however, this study was deemed not acceptable because no data were submitted to substantiate percent of absorption measured.

2. END USE FORMULATIONS

Phosalone EC

Available data indicate that the 34% EC formulation of phosalone when tested for primary eye irritation in 9 New Zealand White rabbits, elicited corneal opacity persisting in 6/6 unwashed and in 2/3 washed treated eyes until day-7. Other eye effects reported were conjunctival puckering (2/6 unwashed), and a hard white residue around the eye (1/6 unwashed and 1/3 washed). All eyes were clear by day-10. Phosalone EC is characterized as moderately irritating to the eye, placing it in Toxicity Category II.

Phosalone EC is characterized as being a highly acutely toxic pesticide. LD50 values calculated at > 480 mg/kg for females and 488 mg/kg for males place this product in Toxicity Category II for oral exposure.

Primary dermal irritation data demonstrate that phosalone EC is mildly irritating to the skin, Toxicity Category IV, and is viewed as being a weak dermal sensitizer.

Phosalone WP

Available data indicate that the 25% WP formulation of phosalone when tested for primary eye irritation in 9 New Zealand White rabbits, elicted corneal opacity persisting in 6/6 unwashed treated eyes until day-7. Slight conjunctival irritation was exhibited in 2 of the washed treated eyes. All eyes were clear by day-10. Phosalone WP is characterized as moderately irritating to the eye.

Phosalone WP is characterized as being a highly acutely toxic pesticide. LD50 values calculated at 480 mg/kg and 600 mg/kg for males only, place this product in Toxicity Category II for oral exposure.

Primary dermal irritation data demonstrate that phosalone WP is mildly irritating to the skin, Toxicity Category IV, and is viewed as being a weak dermal sensitizer.

C. ECOLOGICAL ASSESSMENT

Aquatic Organism Toxicity

Acute toxicity data indicate that technical phosalone is very highly toxic to warmwater fish (bluegill) with an LC50 of 50 ppb and is highly toxic to coldwater fish (rainbow trout) with an LC50 of 630 ppb. Results of an aquatic invertebrate study conducted with Daphnia magna demonstrated that technical phosalone was very highly toxic to this species with an LC50 of 1.2 ppb.

The Agency's estimated environmental concentrations (EEC's) resulting from runoff, drainage, and drift of a single maximum application of phosalone would range from 15 to 138 ppb based upon current use patterns. These estimated concentrations are above the lower aquatic LC50 values discussed above.

Transportation of phosalone into aquatic environments could lead to direct toxicity to fish as well as the loss to fish of their prey base. The Agency is requiring simulated (e.g., mesocosm), actual field testing, or field monitoring studies to ascertain the potential impact of transported phosalone to aquatic environments.

Avian Toxicity

An acute oral avian study indicates that phosalone, when administered orally in a single dose, is slightly or practically nontoxic to birds. The LD50 value for the mallard duck is greater than 2150 mg/kg.

Subacute dietary toxicity studies on mallard ducks and bobwhite quail likewise support findings that phosalone is slightly toxic to birds. The LC50 values calculated for the bobwhite quail and for the mallard duck are 2033 ppm and 1659 ppm respectively. A dietary NOEL was calculated for mallards to be 562 ppm and for bobwhite quail to be 1000 ppm.

Maximum application rates for phosalone range from 1 lb ai/acre to 9 lb ai/acre, depending upon the crop. Estimated foliar residues immediately following a single application would be 125 to 1350 ppm. All use patterns with application rates at 3 lb ai/acre and above would exceed one fifth, 332 ppm, the subacute dietary LC50 value for mallards calculated above.

For both species tested, 50 percent mortality occurred at 1780 ppm. The data suggest that acute effects in the field are unlikely at maximum application rates of 4 lb ai/Acre and below, which would include all current use patterns except for cherries and citrus. A potential for acute field effects may exist for cherries (maximum application rate 8 lb ai/Acre) and citrus (maximum application rate 9 lb ai/Acre). A field study in citrus to characterize this effect is required.

There are no adequate data for assessing the potential hazards of repeated applications or the likelihood of chronic effects. Information is also needed on minimum intervals between repeat applications and experimental data on the effects of phosalone on avian reproduction. After evaluation of these data, field studies in crops other than citrus may be required.

Endangered Species

There are sufficient data to indicate that the current registered uses of phosalone may affect endangered species. In aquatic environments, all maximum application rates for various uses are expected to result in EEC's above the invertebrate LC50 value and above 1/20 the fish LC50 values for the tested species. In terrestrial environments, the EEC's for cherries and citrus applications exceed the NOEL for mallards (562 ppm) and for bobwhite quail (1000 ppm). Concerns are reduced for other uses but are not eliminated because some terrestrial endangered wildlife species could be more sensitive than those that were tested.

Hazards to Non-Target Insect-Pollinators

Available data indicate that phosalone is moderately toxic to honey bees, Apis mellifera, by direct spray contact. Residual contact for wild bees was studied with the leafcutter bee, Megachile pacifica, and the alkali bee, Nomia melanderi. This study demonstrated that phosalone has a low residual toxicity.

D. ENVIRONMENTAL FATE ASSESSMENT

Environmental Characteristics

Phosalone is stable at pH 5 and 7, but is hydrolyzed at a pH of 9 with a half-life of 9 days. Artificial light accelerated degradation in buffered solution at a pH of 5 and in soil. Aerobic soil metabolism studies demonstrated half-life values of 1-7 days. Field dissipation studies showed half-life values of 1-9 weeks. Phosalone was essentially immobile in a soil column test. Based upon this preliminary data phosalone appears unlikely to contaminate ground water. It exhibited moderate accumulation in the bluegill sunfish, with rapid dissipation in untreated waters.

Exposure Incidents

Phosalone is an acetylcholinesterase inhibiting pesticide which may present a hazard to persons reentering treated fields.

The Agency has received a number of poisoning incidents that suggest that phosalone can cause adverse effects to persons entering treated fields and to persons involved in the preparation and application of this pesticide. This evidence is based on poisoning episodes cited in the Pesticide Information Monitoring System (PIMS) and reports received from the California Department of Food and Agriculture (CDFA).

The Pesticide Information Monitoring System lists 12 incidents involving phosalone. However, eleven of these incidents could not conclusively implicate phosalone, because of improper use of equipment and failure to follow recommended safety regulations. The one valid incident involved an fieldworker stripping grape leaves that had been sprayed with phosalone. He was hospitalized for one day then released.

The California Department of Food and Agriculture (CDFA) lists 4 incidents involving phosalone; three applicator poisoning and one fieldworker. No deaths or hospitalizations were reported.

In September 1987, the Agency received notification from CDFA and from the producer of phosalone of several incidents involving fieldworker illnesses during harvesting of grapes. The producer reported that, in three incidents in California vineyards, 37 workers exhibited symptoms of organophosphate poisoning, and that a total of 15 workers were hospitalized. These poisoning incidents occurred in three different vineyards in California, according to the report. Preliminary residue analysis indicated that phosalone levels on foliage ranged up to 95 ppm and residues of its oxygen analog on foliage ranged from 6 ppm to 32 ppm. Residues in leaf debris on the ground were considerably higher (up to 580 ppm phosalone and 75 ppm oxygen analog). Analysis also indicated the presence of residues of other pesticides. These incidents are still under investigation by the State of California and the producer of phosalone.

E. OTHER SCIENCE FINDINGS

Phosalone Metabolites

Phosalone-Oxon

An acute oral LD50 study conducted on the oxygen-analog of phosalone, a known plant and animal metabolite, demonstrated that the oxon was more acutely toxic than its parent. The LD50 values were 36 mg/kg for males and 20 mg/kg for females, which place this metabolite in Toxicity Category I for oral exposure.

Phosalone-Sulfone

A study describing the subchronic effects of phosalone-sulfone 6-chlorobenzoxazolone in rat, was reviewed and found to be unacceptable. Phosalone-sulfone was fed at dietary concentrations equivalent to 0, 5, 15, and 45 mg/kg/day. This study was unacceptable because of no clear toxic effects were shown and there was incomplete reporting of the doses administered and statistical results. No further testing is required, pending evaluation of plant and animal metabolism data.

Emergency Treatment

Current product labeling recommends the use of atropine in conjunction with 2-PAM.

In a study to determine the effectiveness of cholinesterase reactivators as antidotes against a lethal dose of phosalone, P_2S (1-methylpyridyl-2-aldoxime methyl sulfate), an analog of 2-PAM, was found to be more effective than atropine when tested. A combination of the two (10 or 20 mg/kg atropine plus 25 or 50 mg/kg P_2S) was the most effective treatment.

Rotational Crop

A confined rotational crop study performed under greenhouse conditions using ^{14}C-phosalone in loam soil was reviewed and found to be partially acceptable. The study demonstrated that phosalone and/ or its metabolites can accumulate in radishes, beans, potatoes, and wheat planted 5.3 to 7.8 months after soil treatment with phosalone at 3 kg ai/ha.

This study failed to identify residues detected and did not evaluate multiple applications; for potatoes up to 20 lb/acre and for artichokes up to 12 lb/acre can be applied per season.

F. TOLERANCE REASSESSMENT

1. Tolerances Issued

Tolerances have been established for phosalone on a variety of raw agricultural commodities, in meat, fat and meat byproducts (40 CFR 180.263),in processed food (21 CFR 193.340), and in feed (21 CFR 561.300).

2. Residue Data

The residue data reviewed in support of these phosalone tolerances are:

a. Data on the nature of the residue in both plants and animals, including identification of major metabolites and degradates of phosalone.

The nature of the residue in plants is not completely understood. Plant studies reviewed in the initial registration standard either failed to (i) use radiolabeled phosalone; (ii) provide a ^{14}C-balance; or (iii) identify residues in the raw agricultural commodity. Data on plant metabolites are unacceptable because the percentage of characterized metabolites was below accepted standards. Identified metabolites included phosalone, its oxygen-analog, 6-chloro-2-oxobenzoxazoline, and a conjugated glycoside.

The metabolism of phosalone in animals also is not fully characterized. The sole available ruminant metabolism study failed to quantify or characterize ^{14}C-residues in tissues. A goat metabolism study submitted subsequent to issuance of the 1981 registration standard was found to be unacceptable, because greater than 40% of the ^{14}C-activity in milk and in tissues was uncharacterized by TLC and GLC methods.

Metabolism studies in both plants and animals are required.

	Tolerance (ppm)		
Commodity	U.S.	Canadian	Codex
Almond, hulls	50.0	-	-
Apples	10.0	5	5
Dried apple pomace	85.0	-	-
Apricots	15.0	4	-
Dried apricots	-	12	-
Artichokes	25.0	15	-
Cattle, fat	0.25	-	-
Cattle, meat	0.25	-	-
Cattle, mbyp	0.25	-	-
Cherries	15.0	6	10
Citrus fruits	3.0	1.5	1
Citrus pulp	12.0	-	-
Goats, fat	0.25	-	-
Goats, meat	0.25	-	-
Goats, mbyp	0.25	-	-
Grapes	10.0	5	5
Dried grape pomace	45.0	-	-
Hogs, fat	0.25	-	-
Hogs, meat	0.25	-	-
Hogs, mbyp	0.25	-	-
Horses, fat	0.25	-	-
Horses, meat	0.25	-	-
Horses, mbyp	0.25	-	-
Nectarines	15.0	-	-
Nuts	0.1	-	-
Peaches	15.0	4	5
Pears	10.0	2	2
Plums (fresh prunes)	15.0	5	5
Dried prunes	40.0	-	-
Potatoes	0.1(N)	0.1	0.1
Raisins	20.0	-	-
Sheep, fat	0.25	-	0.5
Sheep, meat	0.25	-	0.05
Sheep, mbyp	0.25	-	-
Tea	8.00	-	-

a-shell-free

No Mexican tolerances for phosalone have been established.

Tolerances for residues in or on animal and plant commodities are currently expressed in terms of phosalone *per se*. On receipt of the required data the adequacy of this tolerance expression will be reevaluated. If metabolites are found to be of toxicological concern, the metabolite may be included in the tolerance.

b. Adequate GLC methods (nos. 54A and 54C) are available for data collection and enforcement of established tolerances for phosalone residues in or on raw agricultural commodities and animal tissues. Method no. 54A has previously been determined, in the initial registration standard, to be adequate for data collection and enforcement and is listed in the PAM Vol. II as enforcement method I.

Both methods have undergone successful method tryouts. Modifications of method no. 54A permit detection of phosalone and its o-analog in plant tissue by GLC with electron capture detection.

Phosalone is recovered by all four multiresidue method protocols published by NTIS under order No. PB203734/AS.

c. Storage stability data demonstrate that phosalone and its O-analog are stable in frozen plant tissue for up to three years.

Storage stability data are required to evaluate the stability of phosalone and its metabolites in animal tissues.

If, upon receipt of the required metabolism data, the Agency determines the need to regulate metabolites of phosalone, additional data on the storage stability of the metabolites may be required.

d. Data on the magnitudes and levels of residues of phosalone are sufficient to determine the adequacy of the established tolerance for residues of phosalone in or on potatoes, citrus, apples, pears, apricots, cherries, nectarines, peaches, plums (fresh prunes), dried prunes, grapes, raisins, artichokes, and the fat, meat, and meat by-products of cattle, goats, hogs, horses, and sheep.

Additional data are required to assess the need for food/feed additive tolerances for the following processed products from raw agricultural commodities bearing measurable, weathered residues: potato granules and flakes, chips, and wet and dry peels; and raisin waste and grape juice.

3. Toxicology

The Agency has established a Provisional Acceptable Daily Intake (PADI) at 0.0025 mg/kg/day based on a 6-month dog feeding study in which plasma cholinesterase activity was depressed. Because a NOEL was not established in this study a 100-fold uncertainty factor has been used rather than the 10-fold factor normally applied for cholinesterase inhibition.

The anticipated residue contribution (ARC) to the human diet was calculated based upon anticipated residues obtained from field residue data, processing data, and percent of crop treated data.

The ARC for the United States population is 0.001238 mg/kg/day which occupies 49.5% of the PADI. The two highest calculated exposures based on tolerances and anticipated residues were for non-nursing infants (0.003545 mg/kg/day, 141.8% of the PADI) and for and children under the age of six (0.002768 mg/kg/day, 110.7% of the PADI).

The PADI will be reassessed upon receipt and evaluation of toxicology data enumerated in this standard.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on review and evaulation of all available data and other relevant information on phosalone, the Agency has made the following determinations.

1. Special Review.

The Agency is not placing phosalone into Special Review at this time. The Agency has insufficient information to determine whether the criteria of 40 CFR 154.7 are exceeded for phosalone use patterns. The avian and aquatic field studies are required to determine actual residue levels in the aquatic environment and to assess potential risks to aquatic and avian species.

Rationale: Laboratory data, theoretical calculations and modeling indicate that phosalone use patterns could result in residue levels that would exceed risk criteria for mortality to non-target fish, birds, mammals, and aquatic invertebrates. The aquatic and terrestial field studies that are required will allow the Agency to assess the potential risks.

2. Restricted Use.

The Agency is classifying phosalone products as restricted use pesticides except for products packaged and labeled solely for use around the home.

Products containing phosalone for use on cherries and citrus are restricted due to avian hazards. All use patterns are restricted due to aquatic toxicity. Use is restricted to certified applicators or persons under their direct supervision. Limiting the use to certified applicators will ensure applications by persons knowledgeable of the hazards to wildlife, thereby reducing the potential for adverse effects.

Rationale: Pesticide products may be classified as restricted use if the product, without such restrictions, "may generally cause unreasonable adverse effects on the environment", which can reasonably be prevented by classification for restricted use.

Phosalone is highly toxic to aquatic organisms; for *Daphnia magna* the LC50 is 1.2 ppb. The estimated environmental concentration ranges from 15 to 138 ppb for various uses of phosalone, which far exceeds the lower LC50 value calculated for aquatic invertebrates.

Phosalone applied at a single maximum application on either cherries or citrus would exceed not only 1/5 the LC50 value for mallards, but would also exceed the dietary NOEL for both mallards and bobwhite quail.

The application rates and the area generally treated by the individual homeowner in relation to application rates and area treated by an agricultural user are not expected to cause adverse effects on the environment.

3. Aquatic and Avian Field Testing

The Agency is requiring simulated or actual aquatic field testing unless aquatic residue monitoring studies are conducted and demonstrate that phosalone and its oxygen-analog do not occur in aquatic environments near use sites at concentrations above 0.6 ppb.

Field studies are required for citrus application to evaluate acute hazard to avian and terrestrial mammalian species.

Rationale: These studies are needed to assess risks to these species to determine whether additional regulatory action is warranted.

4. Reentry Interval

The Agency will retain as an interim measure the 24-hour reentry interval required by 40 CFR 170.3, and confirmed by the 1981 Registration Standard. In light of the reported California poisoning incidents, the Agency will accelerate the submission of reentry data on foliar dissipation of residues, and will give such data priority review upon receipt. Based on these data, the registrant must propose a reentry interval, in accordance with Subdivision K Guidelines.

Rationale: Phosalone is a moderately toxic pesticide at the high end of Tox Category II for dermal and oral toxicity. Its uses would involve substantial exposure to fieldworkers. The Agency has received incident data indicating that residues of this pesticide can cause adverse effects to persons entering treated sites. This evidence is based on number of poisoning episodes documented in the Pesticide Information Monitoring System (12) and by reports received from the California Department of Food and Agriculture (4).

The Agency is seriously concerned about the recent fieldworker poisonings in California, which may be attributable to phosalone treatment of grapes. Although the incidents are still under investigation by the California Department of Food and Agriculture and the producer of phosalone, EPA believes it prudent to obtain and review relevant data concerning foliar dissipation as quickly as possible, so that if revisions to the reentry interval or other protective measures are warranted, they can be implemented as soon as possible.

5. Protective Clothing and Equipment

The Agency will require that labels bear statements requiring the use of protective clothing for pesticide handlers and workers reentering treated fields. In addition, the use of human flaggers during aerial application is prohibited, unless they are in an enclosed vehicle such as a pickup truck or a tractor with a completely enclosed cab.

Rationale: Because of the acute toxicity of phosalone and the poisoning incidents cited, specific protective clothing and equipment are required to minimize exposure of field workers, applicators, and flaggers.

6. Significant New Food Uses

The Agency will not approve significant new food uses[3] of phosalone until the required toxicity data have been submitted and evaluated.

3/ Significant new uses as defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will consider as significant an increase in the Theoretical Maximum Residue Contribution of greater than one percent.

Rationale: The residue chemistry and toxicology data bases for phosalone are not complete. Animal and plant metabolism data are required as well as data on various commodities. The required toxicology data include subchronic feeding, chronic feeding, oncogenicity, teratology, 2-generation reproduction, mutagenicity and metabolism testing. (Refer to Appendix I, for a listing of required residue chemistry and toxicology data).

7. Endangered Species Concerns

The Agency will not require endangered species labeling for phosalone at this time. However, the Agency has referred phosalone to the Fish and Wildlife Service to determine if endangered species may be in jeopardy.

Rationale: There are sufficient data to indicate that the current use patterns of phosalone may affect endangered species.

An analysis of pesticides with similar uses to phosalone revealed that a number of endangered species were found to be in jeopardy.

In the aquatic environments, all maximum application rates for the various uses are expected to result in EEC's above the aquatic invertebrate LC50 and above 1/20th the fish LC50 for tested species. These levels indicate potential hazard to fish, aquatic invertebrates, and endangered species.

In the terrestial environments, all uses except ornamentals may result in EEC's that exceed 1/10 the dietary LC50 for mallards. Application rates for citrus in California and in Arizona may have EEC's that approach the actual mallard LC50.

8. Rotational Crop Restriction

The Agency is imposing a 6 month rotational crop restriction for small grain crops and a 12 month rotational crop restriction for root crops and leafy vegetables. If the rotational crop studies for small grains and root crops, which were only partially acceptable, are repeated, these restrictions may be modified.

Rationale: The rotational crop restrictions are required because unidentified residues were detected in a confined rotational crop study at up to 7.8 months rotational intervals following a single maximum application. Multiple applications of phosalone were not evaluated. The Agency believes it is prudent to impose the above restrictions until the results of an additional crop rotational study is evaluated.

9. Groundwater Contamination

Preliminary data indicate that phosalone is unlikely to leach through the soil. The Agency is requiring environmental fate studies to fully characterize phosalone's fate in the environment.

Rationale: A leaching study (unaged portion only) indicates that phosalone was relatively immobile in sandy loam, clay loam, and slit loam. Aerobic metabolism studies demonstrated half-life values of 1-7 days. However the available data are insufficient to fully characterize the leaching potential of phosalone. Additional studies are required.

The Agency has become increasingly concerned about the presence of pesticide chemicals in ground waters of the United States. Although phosalone was not included in the Special Data Call In Notice the Agency issued on March 31, 1984, the Agency is concerned over the potential of phosalone to leach. The data required under this Guidance Document will allow the Agency to characterize the potential of phosalone to contaminate ground water.

10. Tolerance Reassessment. Based on its review of currently available data, the Agency has concluded that:

a. Tolerances for the following commodities are adequately supported: potatoes, citrus, apples, pears, apricots, cherries, nectarines, peaches, plums (fresh prunes), dried prunes, grapes, raisins, artichokes, tree nuts, almond hulls, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep.

b. Additional data are required to assess the need for food/feed additive tolerances for the following products processed from raw agricultural commodities bearing measurable, weathered residues: potato granules or flakes, chips, wet and dry peels; raisin waste; and grape juice. If residues are found to concentrate in these processed foods/feeds, food or feed additive tolerances will be required.

c. The nature of the residue in both plants and animals is not completely understood. If, on receipt of the required metabolism data, the Agency determines that residues of concern in addition to the parent phosalone require regulation, additional methods for data collection and enforcement will be needed. Moreover, additional residue data on crops may be required to measure the level of new metabolites of concern.

d. Crop group tolerances may be established for the Pome Fruit Group at 10 ppm and for the Stone Fruit Group at 15 ppm.

11. Immediate Review of Studies

The Agency has identified certain data that will receive priority review when submitted.

Rationale: Certain data are essential to the Agency's assessment of phosalone. A review of these data may indicate the need for further studies which should be initiated as soon as possible (e.g. tiered studies). The following studies have been identified to receive priority review as soon as they are received by the Agency:

§158.125-Residue Chemistry - Plant Metabolism
- Livestock Metabolism
- Storage Stability Data

§158.130-Environmental Fate- Foliar Dissipation
- Aged Leaching Study

§158.135-Toxicology
- Subchronic 90-Day Feeding (Dog)
- Oncogenicity
- Mutagenicity

§158.140-Reentry Protection- Foliar Dissipation

§158.145-Wildlife and Aquatic Organims
- Terrestial field studies
- Aquatic field studies
- Avian Reproduction

11. Continuation of Registration

While data gaps are being filled, currently registered manufacturing use products (MPs) and end use products (EPs) containing phosalone may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7). Issuance of this standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain Phosalone and bear required labeling, and conform to the product composition, acute toxicity limits, and use patterns requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacting-use products (MPs) must contain phosalone as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurties found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade, manufacture-use products, and end-use products containing phosalone provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products must be labeled for formulation into other manufacturing-use proudcts or into end-use products bearing federally registered uses. Appendix III list all federally registered uses as well as as approved maximum application rates and frequencies.

D. LABELING

All manufacturing-use products and end-use products, must bear appropriate labeling as specified in 40 CFR 162.10, PR Notices 83-2, 83-3, and below. Appendix II contains information on label requirements.

No pesticide product containing phosalone may be released for shipment by the registrant after November 30, 1988, unless the product bears an amended label which complies with the requirements of FIFRA, as specified in this Standard.

No pesticide product containing phosalone may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after November 30, 1989, unless the product bears an amended label which complies with the requirements of FIFRA, as specified in this Standard.

ALL PRODUCTS

1. Ingredients Statement

Registrants of all phosalone products are required to revise their labels to the following format:

ACTIVE INGREDIENT:

Phosalone [S-6-chloro-2,3-dihydro-2-oxobenzoxazol-3-yl methyl
O,O-diethyl phosphorodithioate]............ _____%
INERT INGREDIENTS: .... _____%

MANUFACTURING-USE PRODUCTS

1. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for uses accepted by the U.S. Environmental Protection Agency. Labeling must specify sites for those use patterns listed under Use Patterns as Appendix III. No uses may be included on any label where the registrant fails to agree to comply with the data requirements in TABLE A for that pattern of use.

2. Environmental Hazard Statements

The following revised environmental hazard statement must appear on all manufacturing product labels:

"This pesticide is toxic to fish. Do not discharge effluent containing this pesticide into lakes, streams, ponds, estuaries, oceans, wetlands, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing phosalone to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA".

3. Precautionary Statements

The following revised precautionary statement must appear on all manufacturing product labels:

"HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

"May be fatal if swallowed or absorbed through the skin. Causes eye irritation. May cause allergic skin reactions in some individuals. Do not get into eyes, on skin or on clothing. Wear protective clothing, chemical resistant gloves, and goggles. or faceshield. Avoid breathing fumes or spray mist".

END-USE PRODUCT LABELING

1. Restricted Use Statement

The following restricted use statement must appear on the front panel of all products not intended for or packaged for use around the home.

> "RESTRICTED USE PESTICIDE
> Due to Aquatic Toxicity and Avian Hazard
>
> For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification".

2. Environmental Hazard Statements

The following revised environmental hazard statement must appear on all end-use product labels:

> "This pesticide is toxic to fish. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes".

3. Bee Caution Statements

The following revised bee hazard statement must appear on all end-use product labels:

> "This pesticide is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visting the treatment area".

4. Reentry Statement

The following statement must appear on the labeling of all agricultural end-use products:

> "Do not enter treated areas for 24 hours after application unless the protective clothing specified is worn"

5. Protective Clothing and Equipment

The following statements must appear on the label of all end-use products:

"USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING, LOADING, AND APPLICATION EQUIPMENT, DISPOSAL OF THE PESTICIDE, AND EARLY REENTRY INTO TREATED AREAS: Protective suit of one or two pieces covering all parts of the body except head, hands, and feet; chemical resistant gloves; chemical resistant shoes, shoe covering, or boots; and goggles or face shield. Wear a chemical resistant hood or wide-brimmed hat during airblast application or when overhead exposure will occur".

IF MIXING/LOADING IS PERFORMED USING A CLOSED SYSTEM, THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT MAY BE WORN AS AN ALTERNATIVE: Long-sleeved shirt and long-legged pants; chemical resistant gloves; chemical resistant apron; shoes and socks. Goggles or face shield must be worn if the system is under pressure.

IF APPLICATION IS PERFORMED USING AN ENCLOSED CAB OR COCKPIT THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT MAY BE WORN AS AN ALTERNATIVE: Long-sleeved shirt and long-legged pants; shoes and socks. Chemical resistant gloves must be available in the cab or cockpit and must be worn when exiting. This clothing is inadequate to protect you during equipment repair or cleaning, reentry, or pesticide disposal work. During equipment repair or cleaning, reentry, or pesticide disposal work, full protective clothing must be worn.

IMPORTANT! If pesticide comes in contact with skin, wash off with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or toileting.

AFTER WORK: Before removing gloves, wash them with soap and water. Take off all work clothes and shoes. Shower using soap and water. Wear clean clothes. Do not reuse contaminated clothing. Personal clothing worn during work must be laundered separately form household articles. Store protective clothing separately from personal clothing. Clean or launder protective clothing after each use. Clothing that becomes heavily contaminated or drenched must be destroyed according to state and local regulations. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

DURING AERIAL APPLICATION, HUMAN FLAGGERS MUST BE IN TOTALLY ENCLOSED VEHICLE.

6. Rotational Crop Statement

The following revised rotational crop statements must appear on all end-use product labels:

> " Do not rotate any leafy or root crop vegetable on soil treated with phosalone for at least 12 months".

> " Do not rotate any small grain crops on soil treated with phosalone for at least 6 months".

7. Precautionary Statements

The following revised precautionary statement must appear on all end-use products labels:

"HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

"May be fatal if swallowed or absorbed through the skin. Causes eye irritation. May cause allergic skin reactions in some individuals. Do not get into eyes, on skin or on clothing. Wear protective clothing, chemical resistant gloves, and goggles. Avoid breathing fumes or spray mist".

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing the pesticide identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

4/ Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products.

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[4]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[5], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

5/ If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

2. If eligible for the formulator's exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[6]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and # 152.85) to submit generic data in response to a DCI notice if the registrant

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6/ Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form

8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA

7/If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

Form 8580-1), with appropriate attachments.[7]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

Within 9 months from the receipt of this document, you must submit to the Product Manager:

> Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

E. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

F. Addresses

The required information must be submitted to the following address:

Dennis H. Edwards (PM 12)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR THE TECHNICAL GRADE OF PHOSALONE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data Be Submitted?	Time Frame For Submission
158.120 Product Chemistry						
Product Identity and Composition						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	No	N/A	Yes/2	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No	N/A	Yes/3	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	TGAI	All	No	N/A	Yes/4	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No	N/A	Yes/5	6 Months
63-3 - Physical State	TGAI	All	No	N/A	Yes/5	6 Months
63-4 - Odor	TGAI	All	No	N/A	Yes/5	6 Months
63-5 - Melting Point	TGAI	All	No	N/A	Yes/5,6	6 Months
63-6 - Boiling Point	TGAI	All	No	N/A	Yes/5,7	6 Months
63-7 - Density, Bulk Density, or	TGAI	All	No	N/A	Yes/5	6 Months
63-8 - Solubility	TGAI or PAI	All	No	N/A	Yes/5	6 Months
63-9 - Vapor Pressure	TGAI or PAI	All	No	N/A	Yes/5	6 Months
63-10 - Dissociation Constant	TGAI or PAI	All	No	N/A	Yes/5	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All	No	N/A	Yes/5,8	6 Months
63-12 - pH	TGAI	All	No	N/A	Yes/5,9	6 Months
63-13 - Stability	TGAI	All	No	N/A	Yes/5	6 Months
Other Requirements:						
64-1- Submittal of samples	TGAI or PAI	All	No	N/A	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR THE TECHNICAL GRADE OF PHOSALONE

§158.120 Product Chemistry-Continued

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

3/ A detailed discussion of all impurities that are or may be present at $\geq$0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

4/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

5/ Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, K_{OW}, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D must be submitted.

6/ Data needed if the technical chemical is a solid at room temperature.

7/ Data needed if the technical chemical is a liquid at room temperature.

8/ Required if the technical chemical is organic and non-polar.

9/ Required if the test substance is dispersible with water.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry					
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	Partially	00006386, 00006675 00062878, 00062879 05013895, 05014688 00006125, 00006791 05016356.	Yes/1	18 Months
- Livestock	PAIRA & Plant Metabolites	Partially	00006715, 00006974 00064523.	Yes/2	18 Months
171-4 - Residue Analytical Methods					
- Plant and Animal Residues	TGAI & Metabolites	Yes	05016979, 00006979 00006703, 00006129 00006762, 00006105 00053758, 00006083 40259201, 00006678 00006700, 00006701 00086695, 00062880 00064522, 00064524 00064525, 00064528 00064530, 00064634 00006383, 00109468 00144442, 00159274 05003635, 05007744 05007745, 05008190 05009309, 05016356 05016979.	No/3	
171-4-Storage stability data	PAI and Metabolites	Partially	00062881, 00006968 05014548, 00006698 00006113.	Yes/4,5	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
- Crop Field Trials					
- Root and Tuber Vegetables Group					
o Potatoes	TEP	Partially	00006395, 00006576.	Yes/6, 11	18 Months
- Citrus Fruit Group	TEP	Yes	00006511, 00057510 00057511.	No/11	
-Pome Fruit Group					
o Apples	TEP	Yes	00006707, 00006388 00006783, 00006711 00006084, 00006712 00086695.	No/11	
o Pears	TEP	Yes	00006714, 00006392.	No/11	
-Stone Fruit Group					
o Apricots	TEP	Yes	00006194, 00006195, 00006196, 00006197, 00006198, 00006483.	No/11	
o Cherries	TEP	Yes	00006194, 00006195, 00006196, 00006197, 00006198, 00006389, 00006484.	No/11	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
- Crop Field Trials					
-Stone Fruit Group (continued)					
o Nectarines	TEP	Yes	00006194, 00006195, 00006196, 00006197, 00006198, 00006485.	No/11	
o Peaches	TEP	Yes	00006194, 00006195, 00006196, 00006197, 00006198, 00006391, 00006486, 00035788.	No/11	
o Plums (fresh prunes)	TEP	Yes	00006194, 00006195, 00006196, 00006197, 00006198, 00006487, 00006769.	No/11	
-Small Fruits and Berries Group					
o Grapes	TEP	Partially	00006390, 00006480, 00006707, 00006708, 00006713.	Yes/7,11	
o Tree Nuts Group	TEP	Yes	00006358, 00006511, 00098485.	No/11	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry- contined					
171-4-Magnitude of the Residue-Residue Studies for Each Food Use					
-Crop Field Trials					
-Miscellaneous Commodities					
o Artichokes	TEP	Yes	00006964, 00057508 00034721.	No/11	
o Tea	TEP	Partially	00006209, 00006210 00006735.	Yes/8, 11	18 Months
-Meat/ Milk/ Poultry/ Eggs	TGAI or Plant Metabolite	Yes	00064524, 00006978 00006972, 00006973 00006974, 00006975 00006971, 00006071 00006761, 00006792 00006120, 00006123 00006717, 00006073.	No/9, 10	

1/ The uptake, distribution and metabolism of phosalone must be studied in almonds, apples, and potatoes following multiple foliar treatments with ^{14}C-ring-labeled phosalone at rates sufficiently high to permit complete characterization of ^{14}C-residues in mature almond hulls and nutmeats, apples, and potato tubers. Samples must be collected at the minimum permissible interval after the last treatment in accordance with registered uses (0-day-potatoes; 14 days-apples; 60 days-almonds). Almond samples should also be collected immediately after the last treatment and after 30 days to adequately represent registered uses on other tree nut crops (filberts, pecans and walnuts). Representative samples from these tests must also be analyzed by enforcement methods currently in use to ascertain that the methods are capable of adequately recovering and quantifying all residues of concern.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

§158.125 Residue Chemistry-Continued

2/ Metabolism studies using ruminants and poultry must be submitted. Animals must be dosed for 3 days with ^{14}C-ring-labeled phosalone at a level sufficiently high to permit complete identification and quantification of ^{14}C-residues. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, muscle and fat. Samples from these studies must also be analyzed using enforcement methods currently in use to ascertain that the methods are capable of adequately recovering and quantifying all residues of concern. [It should be noted that if metabolism in ruminants or poultry is found to differ significantly from that in rats, additional metabolism data for swine may be required.]

3/ No additional data are required at present. It should be noted, however, that if the requested metabolism studies indicate the need to collect data for or regulate metabolites of phosalone, additional methods for data collection and/or enforcement may be required.

4/ Samples of fat, muscle, liver, milk, and eggs must be fortified with phosalone, sampled and analyzed immediately, stored frozen for the time periods equivalent to those used in all previously-submitted feeding studies, and reanalyzed.

5/ If, on receipt of the required metabolism data, the Agency determines the need to collect data for or regulate metabolites of phosalone, additonal storage stability data may be required.

6/ Data must be submitted depicting residues in granules or flakes, chips, and wet and dry potato peel processed from potatoes bearing measurable, weathered residues. If residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed. It may be necessary to use exaggerated rates to obtain measurable residues in the raw agricultural commodity.

7/ Data depicting residues in raisin waste and juice processed from grapes bearing measurable, weathered residues. If residues concentrate in either of these processed commodities, appropriate food/feed additive tolerances must be proposed.

8/ The registrant must submit copies of labels for all phosalone formulations (accompanied by English translations) that are used on tea in tea-producing countries that export to the United States.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B	Yes	00006067	No	
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B	Yes	00006665	No	
161-3 - On soil	TGAI or PAIRA	A	Yes	00006666	No	
161-4 - In Air	TGAI or PAIRA	A	No		No/1	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	Yes	05009356, 00006666 05008305, 00006664 00006770, 00006649 00006385, 00006791	No	
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Partially	05009356	No/2	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	A	No		No/1	
162-4 - Aerobic Aquatic	TGAI or PAIRA	A	No		No/1	
MOBILITY STUDIES:						
163-1 - Aged leaching study	TGAI or PAIRA	A,B	Partially	00006663	Yes/3	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate - Continued						
163-2 - Volatility (Lab)	TEP	A	No		No/4	
163-3 - Volatility (Field)	TEP	A	No		No	
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	Yes	00137036	No	
164-2 - Aquatic (Sediment)	TEP	A,B	No		No/1	
164-3 - Forestry	TEP	A,B	No		No/1	
164-4 - Combination and Tank Mixes	TEP	A,B	No		No/5	
164-5 - Soil, Long-term	TEP	A	No		No/6	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	Partially	00006664	Yes/7	12 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Reserved/8	
165-3 - Irrigated Crops	TEP	A	No		No/1	
165-4 - In Fish	TGAI or PAIRA	A,B	Yes	00115113, 00115114 00164511	No	
165-5 - In Aquatic Non-Target Organisms	TEP	A,B	No		No/1	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

§158.130 Environmental Fate - Continued

1/ Not required based on the use pattern of phosalone.

2/ Data which will be obtained from the leaching study (163-1) will be used to supplement existing data on aerobic soil metabolism.

3/ A column leaching study on aged phosalone is required. The column should be leached with 1/2 inch water (preferably 0.01 - 0.02 N calcium chloride solution) per day for a minimum of 45 days. Adequate identification of leached residues in soil and eluate is required. Leaching study conducted on unaged phosalone was acceptable.

4/ This study is not required because of the low vapor pressure of phosalone ($<0.5 \times 10^{-6}$ mm Hg at 24°C).

5/ Tank mix data requirements are not being imposed.

6/ A long term soil study is not required because of the rapid dissipation rate of phosalone.

7/ Confined rotational crop study on leafy vegetables is required.

8/ Reserved pending results of confined crop rotational study.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B	Yes	00006716, 05007746 00006643	No	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B	Yes	05007746, 00006643	No	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A,B	No		No/1	
81-7 - Delayed Neurotoxicity - Hen	TGAI	A,B	Yes	00137037, 00137038	No	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding:	TGAI					
- Rodent, and		A,B	No		No/2	
- Non-rodent (Dog)		A,B	Partially	00006684	Yes/3	
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B	Yes	00115115	No	
82-3 - 90-Day Dermal - Rabbit	TGAI	A,B	No		No/4	
82-4 - 90-Day Inhalation:	TGAI					
- Rat		A,B	No		No/5	
82-5 - 90-Day Neurotoxicity:	TGAI					
- Hen		A,B	No		No/6	
-Mammal		A,B	No		No/6	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species:	TGAI					
- Rodent, and		A,B	Yes	00006202	No	
- Non-rodent (Dog)		A,B	Partially	00006203	Reserved/7	
83-2 - Oncogenicity - 2 species:	TGAI					
- Rat (preferred), and		A,B	No		Yes/8	50 Months
- Mouse (preferred)		A,B	Partially	00065653	Yes/8,9	50 Months
83-3 - Teratogenicity - 2 species:	TGAI					
- Rat		A,B	No		Yes	15 Months
- Rabbit		A,B	No		Yes	15 Months
83-4 - Reproduction - Rat 2-generation	TGAI	A,B	No		Yes	39 Months
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A,B	No		Yes/10	9 Months
84-2 - Structural Chromosomal Aberration	TGAI	A,B	No		Yes/10	12 Months
84-4 - Other Genotoxic Effects	TGAI	A,B	No		Yes/10	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A,B	No		Yes	24 Months
85-3 - Dermal Absorption	TGAI	A,B	No		Yes	

1/ Not required based on particle size analysis.

2/ Although an adequate subchronic rodent study is not available, this study will not be required since an adequate chronic rodent study is available.

3/ A special subchronic study is required in the dog to determine a NOEL for cholinesterase inhibition, since a NOEL was not determined for this effect in any dog study.

4/ Due to the present use patterns of phosalone and the adequacy of the 21-day dermal study a 90-day study is not required at this time.

5/ Because of its physical characteristics, no significant inhalation hazard is anticipated from the manufacture and use of phosalone.

6/ This study is not required because acute neurotoxicity study was negative.

§158.135 Toxicology - Continued

7/ This study did not establish definitive no-effect-levels for cholinesterase inhibition in plasma, erythrocyte, and brain tissue.

A special subchronic dog feeding study is required in lieu of a new chronic dog feeding study. This study must establish definitive no-effect levels for cholinesterase inhibition in three compartments--plasma, erythrocyte, and brain tissue. A new chronic study is deferred pending the results of the subchronic study.

8/ Registrants who conduct chronic feeding and/or oncogenicity studies should inform the Agency in writing of the dosage levels planned and their reasons for believing that the highest dose approaches or equals the Maximum Tolerated Dose observed in subchronic or range finding studies, and must also consult with the Agency to determine that the appropriate dosage levels are being used in the chronic feeding and/or oncogenicity studies. If EPA subsequently determines that the study was conducted using a dosage rate that was too low to assess long-term effects, the study may be deemed not to satisfy the data requirement.

9/ Historical control data are required on the incidence of leiomyomas and leiomyosarcomas of the uterus and Harderian gland adenomas in female CD-1 mice.

10/ The full minimum battery of mutagenicity assays is required to be submitted. These consist of mammalian in vitro point mutation, a mammalian in vitro cytogenetics test and at least one test for DNA damage/repair.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	ABEF	Partially	05005243, 05003635 05001343, 05007744 05007745, 05008190 05021646.	Yes/1	15 Months
132-1 - Soil Dissipation	TEP	A	No		Yes/2	27 Months
133-3 - Dermal Exposure	TEP	ABEF	No		No/3	
133-4 - Inhalation Exposure	TEP	ABEF	No		No/3	
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A,B	No		Yes	12 Months
201-1 - Drift Field Evaluation	TEP	A,B	No		Yes	12 Months

1/ This study must be conducted in accordance with Subdivision K of the Pesticide Assessment Guidelines. Specifically, the study must be conducted in California, under hot, dry conditions representative of worst case exposures. Testing must be done on grapes, and residues must be analyzed for phosalone, its oxygen analog and other toxic degradates, at intervals of 1, 2, 5, 7, 14, 21, 28, 35, 60 and 90 days after last treatment.

2/ Soil dissipation data are required only for uses where workers will be exposed directly to substantial quantities of soil during their work activity, for example use on potatoes where hand harvesting will be performed.

3/ Human exposure monitoring data may be submitted at the registrant's option. If dermal exposure data are submitted, inhalation exposure data must also be submitted.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additionl Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B	Partially	00115116	No/1	
71-2 - Avian Subacute Dietary Toxicity	TGAI					
- Upland Game Bird, and		A,B	Yes	00115117	No	
- Waterfowl		A,B	Yes	00115118	No	
71-3 - Wild Mammal Toxicity	TGAI	A,B	No		No/2	
71-4 - Avian Reproduction	TGAI					
- Upland Game Bird, and		A,B	No		Yes	24 Months
- Waterfowl		A,B	No		Yes	24 Months
71-5 - Simulated Field Testing for Birds and Mammals	TEP	A,B	No		No	
71-5 - Actual Field Testing for Birds Mammals	TEP	A,B	No		Yes/3	6 Months [protocol] 30 Months (citrus)
					Reserved/4	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity						
- Coldwater Fish Species, and	TGAI	A,B	Yes	00115119	No	
	TEP	A,B	Yes	40094602	No	
- Warmwater Fish Species	TGAI	A,B	Yes	00115120	No	
	TEP	A,B	Yes	40094602	No	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B	Yes	00115121	No	
	TEP	A,B	No		Yes/5	9 Months
72-3 - Acute Toxicity to Estuarine and Marine Organisms						
- Fish	TGAI	A,B	No		Yes/6	12 Months
	TEP	A,B	No		Reserved/7	
- Oyster	TGAI	A,B	No		Yes/6	12 Months
	TEP	A,B	No		Reserved/7	
- Shrimp	TGAI	A,B	No		Yes/6	12 Months
	TEP	A,B	No		Reserved/7	
72-4 - Fish Early Life Stage, and	TGAI	A,B	No		Yes/8	15 Months
- Aquatic Invertebrate Life-Cycle	TGAI	A,B	No		Yes/8	15 Months
72-5 - Fish - Life-Cycle	TGAI	A,B	No		Reserved/9	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product					
- Fish		A,B	Yes/10	00164511	No	
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	A,B	No		Yes/11	6 Months [protocol] 48 Months
- Actual Field Testing -Aquatic Organisms	TEP	A,B	No		Yes/11	6 Months [protocol] 48 Months
- Aquatic Residue Monitoring Study	TEP	A,B	No		Yes/11	6 Months [protocol] 24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

§158.145 Wildlife and Aquatic Organisms - Continued

1/ This study was not fully acceptable. However, the slight toxicity demonstrated and other avian data reviewed do not indicate a need for repeating this study.

2/ No requirement currently exists.

3/ Actual field testing with birds and mammals is required as per 40 CFR 158.145, to support the use of end-use products containing phosalone on citrus in California and Arizona. The design of the field study must include appropriate methods, such as thorough carcass searching, to determine whether there is pesticide-induced mortality and, if so, the extent of mortality. A protocol for conducting the field study should be submitted to the Agency for review and approval prior to the initiation of the study. A Guidance Document is available from the Agency, which outlines an acceptable approach to these studies. The Agency encourages registrants to consult with EEB staff for assistance as needed.

4/ Actual field testing with birds and mammals is required, as per 40 CFR 158.145, to support the use of phosalone products on any crops where the estimated environmental concentrations (EEC'S) exceed the effect levels, if any, that are determined for the more sensitive species in the required avian reproduction tests. Unless actual residue and residue decline data that are applicable to wildlife food sources (e.g., foliar and insect residues) are submitted, EEC's will be estimated based on initial residues from the EEB nomograph, the minimum spray interval for the particular use, and the maximum half-life for foliar dissipation.

The Agency will determine which crops need to be tested after receipt and evaluation of avian reproduction study.

The design of the field studies must include appropriate techniques to determine the potential field effects on reproduction and populations of birds and mammals in a multiple year study. Protocols for conducting field studies should be submitted to the Agency for review and approval prior to the initiation of the studies. A Guidance Document is available from the Agency, which outlines an acceptable approach to these studies. The Agency encourages registrants to consult with EEB staff for assistance, as needed.

5/ Required to support all crop uses because EEC's on technical phosalone exceed the aquatic invertebrate LC50.

6/ Required to support use on citrus because of potential exposure of estuarine/marine environments through runoff, drainage, and drift.

7/ Reserved pending the results of acute toxicity testing with technical phosalone on marine/estuarine organisms. Required if such testing results in LC50 value(s) that is (are) below the EEC in estuarine/marine environments.

8/ Required to support all crop uses because the acute toxicity of technical phosalone is less than 1 mg/L and because the EEC in water is greater than 0.01 times the acute LC50.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

§158.145 Wildlife and Aquatic Organisms - Continued

9/ Reserved pending the results of fish early life stage and aquatic invertebrate life-cycle tests.

10/ Data submitted under §158.130 guideline series 165.4, accumulation in fish, satisfies this requirement.

11/ Simulated or actual field testing with aquatic organisms is required unless aquatic residue monitoring studies are conducted and demonstrate that phosalone and phosalone-oxon do not occur in aquatic environments near use sites at concentrations above 0.6 ppb. If aquatic residue studies are conducted, they must include pecans as a high use crop and citrus (AZ/CA) or cherries as a high rate crop, with residue studies on other crops reserved pending the results. For each use pattern, multiple independent sites are to be monitored. Each site is to be located in an area where there is a maximum potential exposure due to soil type, proximity to aquatic habitats, and percentage of the local area crop treated with phosalone. Residues must be monitored in receiving water and should be monitored in runoff or drainage water, if feasible. Protocols should be submitted to the Agency for review and approval prior to the initiation of the monitoring studies.

If aquatic residue monitoring studies are not conducted, or show aquatic concentrations greater than 0.6 ppb, then mesocosm studies are preferred and would support all use patterns. Alternatively, full field studies may be conducted in pecans and walnuts to support these uses. Additional full field studies for other use patterns are reserved, pending an evaluation of the results for pecans and walnuts and an analysis of their applicability to support other crop uses. For either mesocosm or full field studies the study design must include appropriate techniques to determine acute mortality and effects on productivity and diversity of fish and aquatic invertebrates. Protocols for conducting residue monitoring, mesocosm, or full field studies should be submitted to the Agency for review and approval prior to the initiation of the study. A Guidance Document is available from the Agency, which outlines an acceptable approach to mesocosm studies. This document also provides relevant, although general, guidance for full field studies, which, if selected in place of mesocosm studies, must include multiple treated ponds and control ponds. The Agency encourages registrants to consult with EEB staff for assistance as needed.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.150 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	EP	All	No		No/1	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	All	No		No/1	
122-1 - Vegetative Vigor	TGAI	All	No		No/1	
122-2 - Aquatic Plant Growth	TGAI	All	No		No/1	
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	All	No		No/1	
123-1 - Vegetative Vigor	TGAI	All	No		No/1	
123-2 - Aquatic Plant Growth	TGAI	All	No		No/1	
TIER III						
124-1 - Terrestrial Field	TEP	All	No		No/1	
124-2 - Aquatic Field	TEP	All	No		No/1	

1/ Not required for insecticides and acaricides.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact toxicity	TGAI	A, B	Yes	00006653, 00006654 00006793, 00139544	No	
141-2 - Honey bee - toxicity of residues on foliage	TEP	A, B	Yes	00006793	No	
141-4 - Honey bee subacute feeding study					Reserved/1	
141-5 - Field testing for pollinators	TEP	A, B	No		No/2	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects					Reserved/3	
142-1 - Aquatic insect life-cycle study					Reserved/3	
142-3 - Simulated or actual field testing for aquatic insects					Reserved/3	
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES					Reserved/3	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSALONE

§158.155 Nontarget Insect- Continued

1/ Reserved pending development of methodology.

2/ As data from the acute and residual test indicated low to moderate toxicity, no further testing is required.

3/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHOSALONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data Be Submitted?	Time Frame For Submission
158.120 Product Chemistry						
Product Identity and Composition						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No	N/A	Yes/2	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	No	N/A	Yes/3	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	No	N/A	Yes/4	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	No	N/A	Yes/5	12 Months
62-2 - Certification of Limits	MP	All	No	N/A	Yes/6	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	All	No	N/A	Yes/7	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	All	No	N/A	Yes/8	6 Months
63-3 - Physical State	MP	All	No	N/A	Yes/8	6 Months
63-4 - Odor	MP	All	No	N/A	Yes/8	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	No	N/A	Yes/8	6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHOSALONE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?a	Bibliographic Citationa	Must Additional Data Be Submitted	Time Frame For Submission
158.120 Product Chemistry (continued)						
63-12 - pH	MP	All	No	N/A	Yes/8,9	6 months
63-14 - Oxidizing or Reducing Action	MP	All	No	N/A	Yes/8,10	6 months
63-15 - Flammability	MP	All	No	N/A	Yes/8,11	6 months
63-16 - Explodability	MP	All	No	N/A	Yes/8,12	6 months
63-17 - Storage Stability	MP	All	No	N/A	Yes/8	15 months
63-18 - Viscosity	MP	All	No	N/A	Yes/8,13	6 months
63-19 - Miscibility	MP	All	No	N/A	Yes/8,14	6 months
63-20 - Corrosion Characteristics	MP	All	No	N/A	Yes/8	15 months
Other Requirements:						
64-1 - Submittal of samples	MP	All	No	N/A	No	

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ The chemical name and nominal concentration of each impurity for which a certified limit is required must be submitted. In addition, the chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredient, the following must also be provided: the product name, trade name, and common name; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

3/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

4/ A detailed discussion of all impurities that are or may be present at ≥0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHOSALONE

§158.120 Product Chemistry-Continued

5/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

6/ Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at ≥0.1% (w/w) and each "toxicologically significant" impurity present at <0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certifications must be submitted on EPA Form 8570 Rev. 2-85.

7/ Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

8/ Physicochemical characteristics (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosion characteristics) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D must be submitted.

9/ Required if the test substance is dispersible with water.

10/ Required if the product contains an oxidizing or reducing agent.

11/ Required if the product contains combustible liquids.

12/ Required if the product is potentially explosive.

13/ Required if the product is a liquid.

14/ Required if the product is a liquid and is to be diluted with petroleum solvents.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHOSALONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	A,B	Yes	00006716, 05007746 00006643	No	
81-2 - Acute Dermal Toxicity - Rabbit	MP	A,B	Yes	05007746, 00006643	No	
81-3 - Acute Inhalation Toxicity - Rat	MP	A,B	No		No/1	
81-4 - Primary Eye Irritation - Rabbit	MP	A,B	No		Yes/2	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	A,B,	Yes	00101506	No	
81-6 - Dermal Sensitization - Guinea Pig	MP	A,B	No		Yes/3	9 Months

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1/ Waived based on particle size analysis. Analysis showed that particle size distribution was not within the respirable range.

2/ Previously accepted study was rereviewed and found to be unacceptable, because it does not allow for an assessment of reversibilty of effects, and does not meet current guidelines.

3/ A recently submitted dermal sensitization study was considered to be inadequate.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END USE PRODUCTS CONTAINING PHOSALONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?^{1}	Bibliographic Citation^1	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	EP	All		N/A	Yes	6 months
61-2 - Description of Beginning Materials and Manufacturing Process	EP	All		N/A	Yes	6 Months
61-3 - Discussion of Formation of Impurities	EP	All		N/A	Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	EP	All		N/A	Yes/2	12 Months
62-2 - Certification of Limits	EP	All		N/A	Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limit	EP	All		N/A	Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	EP	All		N/A	Yes	6 Months
63-3 - Physical State	EP	All		N/A	Yes	6 Months
63-4 - Odor	EP	All		N/A	Yes	6 Months

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END USE PRODUCTS CONTAINING PHOSALONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	EP	All		N/A	Yes	6 Months
63-12 - pH	EP	All		N/A	Yes	6 Months
63-14 - Oxidizing or Reducing Action	EP	All		N/A	Yes	6 Months
63-15 - Flammability	EP	All		N/A	Yes	6 Months
63-16 - Explodability	EP	All		N/A	Yes	6 Months
63-17 - Storage Stability	EP	All		N/A	Yes	15 Months
63-18 - Viscosity	EP	All		N/A	Yes	6 Months
63-19 - Miscibility	EP	All		N/A	Yes	6 Months
63-20 - Corrosion Characteristics	EP	All		N/A	Yes	6 Months
Other Requirements:						
64- 1 - Submittal of samples	EP	All		N/A	No[3]	6 Months

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END USE PRODUCTS CONTAINING PHOSALONE

§ 158.120 Product Chemistry - continued

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing use product. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

2/ Required if source of any active ingredient in end use product is an unregistered pesticide. Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

3/ Samples of the product are required only if the Agency specifically requests them.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING PHOSALONE AS AN EMULSIFIABLE CONCENTRATE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	EC	A,B	Yes	00137882	No	
81-2 - Acute Dermal Toxicity - Rabbit	EC	A,B	Yes	00006689	No	
81-3 - Acute Inhalation Toxicity - Rat	EC	A,B	No		Yes/1	9 Months
81-4 - Primary Eye Irritation - Rabbit	EC	A,B	Yes	00101511	No	
81-5 - Primary Dermal Irritation - Rabbit	EC	A,B,	Yes	00101512	No	
81-6 - Dermal Sensitization - Guinea Pig	EC	A,B	No	00101513	No	

1/ Previously submitted study is unacceptable, because the duration of exposure was inadequate to evaluate this route of exposure.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING PHOSALONE AS A WETTABLE POWDER

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	WP	A,B	Yes	00137881	No	
81-2 - Acute Dermal Toxicity - Rabbit	WP	A,B	Yes	05007746, 00006643	No	
81-3 - Acute Inhalation Toxicity - Rat	WP	A,B	No		Yes/1	9 Months
81-4 - Primary Eye Irritation - Rabbit	WP	A,B	Yes	00101508	No	
81-5 - Primary Dermal Irritation - Rabbit	WP	A,B,	Yes	00101509	No	
81-6 - Dermal Sensitization - Guinea Pig	WP	A,B	No	00101510	No	

1/ Previously submitted study is unacceptable, because the duration of exposure was inadequate to evaluate this route of exposure.

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

   "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

   "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

EPA Compendium of Acceptable Uses

PHOSALONE

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c097701

PHOSALONE*

TYPE PESTICIDE: Insecticide, Acaricide

FORMULATIONS:
Tech (94%)
WP (25%)
EC (1.35 lb/gal, 3 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: Phosalone is classified as a RESTRICTED USE PESTICIDE due to aquatic and avian toxicity for all commercial agricultural products. Phosalone is toxic to fish. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes. Phosalone causes eye irritation and may cause allergic skin reactions; do not get in eyes, on skin or on clothing.

Protective Clothing and Equipment:
Apply phosalone only when wearing the following protective clothing and equipment during mixing/loading, application, repair and cleaning of mixing, loading, and application equipment, disposal of the pesticide, and early reentry into treated areas: Protective suit of 1 or 2 pieces covering all parts of the body except head, hands, and feet; chemical resistant gloves; chemical resistant shoes, shoe covering, or boots; and goggles or face shield. If mixing/loading is performed using a closed system, the following protective clothing and equipment may be worn as an alternative: Long-sleeved shirt and long-legged pants; chemical resistant gloves; chemical resistant apron; shoes and socks. Goggles or face shield must be worn if the system is under pressure. If application is performed using an enclosed cab or cockpit, the following protective clothing and equipment may be worn as an alternative: Long-sleeved shirt and long-legged pants; shoes and socks. Chemical resistant gloves must be available in the cab or cockpit and must be worn when exiting. This clothing is inadequate to protect during equipment repair or cleaning, reentry, or pesticide disposal work. If pesticide comes in contact with skin, wash off with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or toileting. Before removing gloves, wash them with soap and water. Take off all work clothes and shoes. Shower using soap and water. Wear clean clothes. Do not reuse contaminated clothing. Personal clothing worn during work must be laundered separately from household articles. Store protective clothing separately from personal clothing. Clean or launder protective clothing after each use. Clothing that becomes heavily contaminated or drenched must be destroyed according to state and local regulations. Heavily contaminated or drenched clothing cannot be adequately decontaminated. During aerial application, human flaggers must be in totally enclosed vehicle.

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*O,O-diethyl S-[(6-chloro-2-oxobenzoxazolin-3-yl)methyl] phosphorodithioate

GENERAL WARNINGS AND LIMITATIONS (continued)

Bee Caution:

Phosalone is toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product if bees are visiting the treatment area.

Reentry:

Do not enter treated areas for 24 hours after application unless protective clothing is worn.

Agricultural Crop Tolerances (other than those listed in the text):

Brazil nuts	0.05 (N) ppm
Butternuts	0.05 (N) ppm
Cashews	0.05 (N) ppm
Chestnuts	0.05 (N) ppm
Hickory nuts	0.05 (N) ppm
Macadamia nuts (Bush nuts)	0.05 (N) ppm
Tea, dried	8.0 ppm

Dairy, Livestock, and Poultry Tolerances:

Cattle (fat, meat, mbyp)	0.25 ppm
Goats, (fat, meat, mbyp)	0.25 ppm
Hogs (fat, meat, mbyp)	0.25 ppm
Horses (fat, meat, mbyp)	0.25 ppm
Sheep (fat, meat, mbyp)	0.25 ppm

Definition of Terms:

Claims for pest control limited to suppression of population are indicated by an entirely parenthesized pest name.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

TERRESTRIAL FOOD CROP

(Agricultural Crops)

General Warnings and Limitations: Do not rotate any leafy or root crop vegetable on soil treated with phosalone for at least 12 months. Do not rotate any small grain crops on soil treated with phosalone for at least 6 months. The 25 percent wettable powder and the 3 pound per gallon emulsifiable concentrate products are for agricultural or commercial use, and are suitable for use in power operated ground sprayers, including concentrate sprayers and by aircraft. The 1.35 pound per gallon emulsifiable concentrate products may be applied using hand held pressure sprayers or small power sprayers. The use of surfactants (wetting agents) are not recommended. Crop injury resulting from adverse environmental conditions may be aggravated by emulsifiable products. Do not allow livestock to graze on cover crops in treated orchards or nut groves. Do not feed treated cover crops to livestock.

/03001AA	Almond		0.1 (N) ppm (almonds) 50 ppm (hulls) 60 day preharvest interval. Do not apply more than 6 pounds per acre per season. Do not apply more than once during the fruiting season and do not exceed 3 pounds per acre. Apply a minimum of 2 pounds per acre per application. Cover sprays applied as concentrate sprays, dilute (400 to 600 gallons per acre) or with suitable pressure sprayers (hand held tank or small power sprayers). CA (24-C) CA800158. Aerial application, apply in minimum of 20 gallons of water per acre. CA reentry 7 days.
ITAMABA	Peach twig borer	0.5-0.75 lb/ 100 gal or 2-3 lb/A (25% WP) (3 lb/gal EC) or 2.4-3.2 g/gal (1.35 lb/gal EC)	Foliar application.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Almond (continued)		
ILAVACA	Brown mite	0.5-0.75 lb/gal or 2-3 lb/A (3 lb/gal EC) or 2.4-3.2 g/gal (1.35 lb/gal EC)	Foliar application. Do not apply in areas of phosphate resistance.
ILAVBAA ILAVBEA	Pacific spider mite Twospotted spider mite	0.5 lb/100 gal or 2-3 lb/A (3 lb/gal EC) or 2.4 g/gal (1.35 lb/gal EC)	Foliar application. Do not apply in areas of phosphate resistance.
/04001AA	Apple		10 ppm (apples) 85 ppm (dried apple pomace) 14 day preharvest interval. Do not apply more than 17.5 pounds per acre per season. Some russeting of golden delicious and other yellow varieties may occur in some areas. Use low rates for preventative applications and high rates for severe infestations. Time applications to local pest control programs. Cover sprays are applied as concentrate sprays, dilute (400 to 600 gallons per acre) or with suitable pressure sprayers (hand held tank or small power sprayers).
IRACAAA ITBUCSA	Aphids Codling moth	0.25-0.5 lb/100 gal or 1-2 lb/A (25% WP) (3 lb/gal EC) or 1.2-2.4 g/gal (1.35 lb/gal EC)	Foliar application.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Apple (continued)		
INASAVA	Plum curculio	0.5-1 lb/100 gal or 2-4 lb/A (25% WP) (3 lb/gal EC) or 2-4.2 g/gal (1.35 lb/gal EC)	Foliar application.
ILAVBEA	Twospotted spider mite	0.5-1 lb/100 gal or 2-4 lb/A (3 lb/gal EC) or 2-4.2 g/gal (1.35 lb/gal EC)	Foliar application. Do not apply in areas of phosphate resistance.
ITBUAPA	Redbanded leaf-roller	0.375-1 lb/100 gal or 1.5-4 lb/A (3 lb/gal EC) or 1.6-4.2 g/gal (1.35 lb/gal EC)	Foliar application. Do not apply in areas of phosphate resistant mites.
ILAVASA	European red mite		
ITBCBSA	Green fruitworm	0.375 lb/100 gal or 1.5 lb/A (3 lb/gal EC) or 1.6 g/gal (1.35 lb/gal EC)	Foliar application.
IOBMAQA	Apple maggot	0.5-1 lb/100 gal or 2-4 lb/A (25% WP) (3 lb/gal EC) or	Foliar application.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Apple (continued)		
		2.4-4 g/gal (1.35 lb/gal EC)	
ILAJAKA	Apple rust mite	0.56-1 lb/ 100 gal or 2.1-4 lb/A (3 lb/gal EC) or 2.4-4 g/gal (1.35 lb/gal EC)	Foliar application. Control obtained when used in a seasonal program.
/05001AA /05003AA /05004AA	Apricot Nectarine Peach		15 ppm (apricot, nectarine, peach) 7 day preharvest interval. Apply in seasonal program as required, but do not apply more than 12 pounds per 20 pounds emulsifiable concentrate per acre per season. Cover sprays are applied as concentrate sprays, dilute sprays (400 gallons per acre) or with suitable power sprayers (hand held tank or small power sprayers). CA (24-C) CA800158. Aerial application, apply in minimum of 20 gallons of water per acre. CA reentry 7 days.
ITAMABA ITBUCJA	Peach twig borer Oriental fruit moth	0.5 lb/100 gal or 2 lb/A (25% WP) (3 lb/gal EC) or 2-2.4 g/gal (1.35 lb/gal EC)	Foliar application.
IRACAAA	Aphids	0.25-0.5 lb/ 100 gal or	Foliar application.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Apricot cluster (continued)		
		1-2 lb/A (25% WP) (3 lb/gal EC) or 1.2-2.4 g/gal (1.35 lb/gal EC)	
ILAAABA ILAVASA ILAVBEA ILAVACA	Mites European red mite Twospotted spider mite Brown almond mite	0.75-1 lb/100 gal or 3-4 lb/A (3 lb/gal EC) or 3.2-4.2 g/gal (1.35 lb/gal EC)	Foliar application. Do not apply in areas of phosphate resistance.
IRAFAAA INASAVA	Leafhoppers Plum curculio	0.5-1 lb/100 gal or 2-4 lb/A (25% WP) (3 lb/gal EC) or 2-4.2 g/gal (1.35 lb/gal EC)	Foliar application.
/13018AA	Artichoke		25 ppm 7 day preharvest interval. Do not apply more than 12 pounds per acre per season. Apply by air (5 to 10 gallons) or ground equipment (50 to 100 gallons). Apply in seasonal program as required.
IRACAAA IOABAMA	Aphids Chrysanthemum leafminer	2 lb/A (3 lb/gal EC)	Foliar application.
ITBLAAA	Plume moths	1-2 lb/A (3 lb/gal EC)	Foliar application.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/05002AA	Cherry		15 ppm 7 day preharvest interval. Apply in seasonal program as required, but do not exceed 12 pounds wettable powder or 20 pounds emulsifiable concentrate per acre. Cover sprays are applied as concentrate or dilute (600 to 800 gallons per acre). CA (24-C) CA800158. Aerial application, apply in minimum of 20 gallons of water per acre. CA reentry 7 days.
ITBUAGA	Fruittree leafroller	0.375-1 lb/100 gal or 3-8 lb/A (25% WP) (3 lb/gal EC)	Foliar application.
IOBMALA	Cherry fruit fly	0.5 lb/100 gal or 4 lb/A (25% WP) (3 lb/gal EC)	Foliar application.
/03005AA	Filberts (Hazelnuts)		0.5 (N) ppm (filberts (hazelnuts)) Full cover spray applying a minimum of 1.5 pounds per acre. Use limited to OR and WA.
IRACCPA	Filbert aphid	0.375-0.56 lb/100 gal or 1.5-3 lb/A (3 lb/gal EC)	Foliar application.
ITBUBIA	Filbert leafroller		
ITBUCUA	Filbertworm		

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/02000AA /02004AA /02006AA	Grapefruit Lemon Orange		3 ppm (citrus fruit) 12 ppm (dried citrus pulp) 14 day preharvest interval. Do not make more than 1 application every 30 days. Do not make more than 2 applications per season. Do not apply more than 25 pounds per acre per season. Apply as a complete cover spray.
ILAVARA	Citrus red mite	0.25-0.375 lb/100 gal or 5-9 lb/A (3 lb/gal EC)	Use limited to CA and AZ. Foliar application. Apply a minimum of 5 pounds per acre to mature trees.
ITBHADA	Orange dog	0.25 lb/100 gal or 1.5-3 lb/A (3 lb/gal EC) or 1.2 g/gal (1.35 lb/gal EC)	Foliar application.
IMOCAOA	Citrus thrips	0.5 lb/100 gal or 2-3 lb/gal (3 lb/gal EC) or 2.4 g/gal (1.35 lb/gal EC)	Foliar application.
IRABAAA	Whiteflies	0.5 lb/100 gal or 3-4.5 lb/A (3 lb/gal EC) or 2.4 g/gal (1.35 lb/gal EC)	Foliar application.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/01014AA	Grapes		10 ppm (raisins) 20 ppm 45 ppm (dried grape pomace) 14 day preharvest interval. Do not apply more than 8 pounds per season. Apply minimum rates for preventative applications and high rates for severe infestations. Use only concentrate applications to grapes intended for packing or canning. Otherwise apply as concentrate or dilute applications (100 to 200 gallons per acre) or with suitable pressure sprayer (hand held tank or small power sprayer). Time applications to local pest control programs, repeat as needed. CA (24-C) CA800158. Aerial application, apply in minimum of 20 gallons of water per acre. CA reentry 7 days.
IRAFADA	Grape leafhopper	1-2 lb/100 gal or 2-4 lb/A (25% WP)	Use limited to CA. Foliar application. On varieties where residue of spray powder is objectionable do not apply after "buckshot" stage of berry development.
IRAFAAA	Leafhoppers	0.75-1.5 lb/ 100 gal or 1.5-3 lb/A (3 lb/gal EC) or 3.2-6.4 g/gal (1.35 lb/gal EC)	Foliar application.
ILAAABA	Mites	1-2 lb/100 gal or 2-4 lb/A (3 lb/gal EC) or 4.2 g/gal (1.35 lb/gal EC)	Foliar application.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Grapes (continued)		
ITBUCWA	Grape berry moth	0.75.1.5 lb/ 100 gal or 0.75-2.25 lb/A (3 lb/gal EC) or 3.2-6.4 g/gal (1.35 lb/gal EC)	Foliar application.
IRAVAJA	Grape phylloxera	0.5-0.75 lb/ 100 gal or 1-1.5 lb/A (3 lb/gal EC) or 2.4-3.2 g/gal (1.35 lb/gal EC)	Foliar application.
ITBUBCA	Omnivorous leafroller	1-2 lb/100 gal or 2-4 lb/A (3 lb/gal EC)	Foliar application. Ground equipment only.
	Lemon		See Grapefruit cluster.
	Nectarine		See Apricot cluster.
	Orange		See Grapefruit cluster.
	Peach		See Apricot cluster.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/04003AA	Pear		10 ppm 14 day preharvest interval. Do not apply more than 17.5 pounds per acre per season. Use low rates for preventative applications and high rates for severe infestations. Time applications to local pest control programs. Cover sprays are applied as concentrate sprays, dilute (400 to 600 gallons per acre) or with suitable pressure sprayers (hand held or small power sprayers).
IRAXALA	Pear psylla	1.25 lb/100 gal or 3 lb/A (25% WP) or 0.75 lb/100 gal or 3 lb/A (3 lb/gal EC) or 3.2 g/gal (1.35 lb/gal EC)	Foliar application.
IRACAAA	Aphids		
ITBUCSA	Codling moth		
ILAVASA	European red mite		
ITBCBSA	Green fruitworm		
INASAVA	Plum curculio		
ITBVAPA	Redbanded leafroller		
ILAVBEA	Twospotted spider mite		

Refer to these pests under Apple for rates of application and use limitations.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/03008AA	Pecan		0.05 (N) ppm Do not apply after shuck split. Do not apply more than 20 pounds per acre per season. Do not tank mix with disulfoton. Cover sprays are applied by aircraft (5 to 10 gallons per acre), concentrate sprayers, dilute sprayers (200 to 400 gallons per acre) or with suitable pressure sprayers (hand held tank or small power sprayers). Apply in seasonal programs as required. Aerial application may result in reduced control due to poorer coverage.
IRACAFA	Pecan aphid (*Monellia sp.*)	0.5 lb/100 gal or 1-2 lb/A (3 lb/gal EC) or 2-2.4 g/gal (1.35 lb/gal EC)	Foliar application.
IRACDSA	Black pecan aphid		
ITBUCQA	Hickory suckworm		
ITBMADA	Pecan nut casebearer		
IRAEADA	Pecan spittlebug		
INASBBA	Pecan weevil		
IRAVAHA	(Pecan phylloxera)		

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/05005AA	Plum		15 ppm (plums/fresh prunes) 40 ppm (dried prunes) 7 day preharvest interval. Apply in seasonal programs as required but do not apply more than 12 pounds wettable powder or 20 pounds emulsifiable concentrate per acre per season. Cover sprays are applied as concentrate sprays, dilute sprays (400 gallons per acre) or with suitable pressure sprayers (hand held tank or small power sprayers). CA (24-C) CA800158. Aerial application, apply in a minimum of 20 gallons of water per acre. CA reentry 7 days.
/05006AA	Prune		
IRACAAA	Aphids		
ILAVACA	Brown almond mite		
ILAVASA	European red mite		
IRAFAAA	Leafhoppers		
ILAAABA	Mites		
ITBUCJA	Oriental fruit moth		
ITAMABA	Peach twig borer		
INASAVA	Plum curculio		
ILAVBEA	Twospotted spider mite		

Refer to individual pests under Apricot cluster for use and limitation information.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/14013AA	Potato		0.1 (N) ppm Do not exceed 20 pounds per acre per season. Do not forage or feed vines to livestock. Do not use on sweet potatoes. Do not tank mix with disulfoton. Apply by air (5 gallons per acre) or ground equipment (60 to 150 gallons per acre). Apply in seasonal program as required.
INAMCFA	Colorado potato beetle	0.5-1.5 lb/A (3 lb/gal EC)	Foliar application.
IRACASA	(Buckthorn aphid)		
IRACCUA	(Green peach aphid)		
IRACCHA	(Potato aphid)		
IRAFAJA	(Potato leafhopper)		
ITAMAPA	(Potato tuberworm)		
ITBMCCA	European corn borer	1 lb/A (3 lb/gal EC)	Foliar application.
	Prune		See Plum cluster.
/03009AA	Walnuts (English)		0.05 (N) ppm Do not apply more than 20 pounds per acre per season. Do not apply after the husks have split. Apply a minimum of 1 pound per acre by air blast equipment. Apply complete cover spray (300 to 600 gallons per acre). Apply in seasonal programs as necessary. CA (24-C) CA800158. Aerial application, apply in minimum of 20 gallons of water per acre. CA reentry 7 days.
IRACBHA	Walnut aphid	0.25-0.5 lb/100 gal or 0.75-1.5 lb/A (25% WP) (3 lb/gal EC)	Foliar application.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Walnuts (English)	(continued)	
ITBUCSA	Codling moth	0.5-0.75 lb/ 100 gal or 2.25 lb/A (25% WP) (3 lb/gal EC)	Foliar application.
ILAVBEA	Twospotted spider mite	0.5-0.75 lb/ 100 gal or 2-3 lb/A (3 lb/gal EC)	Foliar application. Do not apply in areas of phosphate resistance.
IOBMAMA	Walnut husk fly	0.5-0.75 lb/ 100 gal or 2.25 lb/A (3 lb/gal EC)	Foliar application. Apply before larval feeding causes the husks to darken or shortly after oviposition.
	TERRESTRIAL NONFOOD CROP		
	(Ornamental Woody Shrubs and Vines)		
/34120AA	Rose		
IRACCKA	Rose aphid	0.5-1 lb/100 gal (3 lb/gal EC)	Foliar application. Apply as cover spray (spray to wet) when pest present and repeat as necessary. Slight injury to leaves may occur.
	(Ornamental Trees)		
/35021AA	Arborvitae		
	Spruce spider mite	0.5-1 lb/100 gal (3 lb/gal EC)	Foliar application. Apply as cover spray (spray to wet) when pest is present and repeat as necessary.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	AERIAL, MOTHPROOFING AND TANK MIX APPLICATIONS		
9001500 AAAAAAA	Aerial Application		
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) All sites	

Listing of Registered Pesticide Products by Formulation

&094.0001 94% technical chemical
phosalone (097701)
000359-00632

&025.0006 25% wettable powder
phosalone (097701)
000359-00626

&101.3512 1.35 lb/gal emulsifiable concentrate
phosalone (097701)
010370-00162

phosalone (097701) plus aromatic petroleum derivative solvent (006501)
034911-00026

&103.0012 3 lb/gal emulsifiable concentrate
phosalone (097701)
000359-00620

(000359-00620) CA800158

9999999 State Label Registrations

AL Reg. No.
000359-05112

AR Reg. No.
000359-05114

AZ Reg. No.
000359-05113

CA Reg. No.
000359-05103 000359-05108

FL Reg. No.
000359-05115

GA Reg. No.
000359-05116

HI Reg. No.
000359-05106

LA Reg. No.
000359-05117

Listing of Registered Pesticide Products by Formulation (continued)

MS Reg. No.
000359-05118

NM Reg. No.
000359-05119

NY Reg. No.
000359-05110 038655-10415

OK Reg. No.
000359-05120

OR Reg. No.
000359-05104 000359-05107

PA Reg. No.
000359-05109

SC Reg. No.
000359-05121

TX Reg. No.
000359-05111 000359-05122

WA Reg. No.
000359-05105

Appendix A-1

Listing of Active Ingredient(s) Found in Combination with the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
006501	aromatic petroleum derivative solvent	--

-- Use Common Name

PHOSALONE

Auxiliary Documentation

None.

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

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b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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  (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

  (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

  (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

  (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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00006071	Totman, L.C.; Imming, R.J.; Woodard, G. (1967) Phosalone: Analysis of Compound Residue in Tissues of Beef Cattle and Sheep. (Unpublished study received Oct 16, 1967 under 9F0759; prepared by Woodard Research Corp., submitted by Rhodia, Inc., New Brunswick, N.J.; CDL:093071-E)
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00006196	Rhodia, Incorporated (1970) Nectarines: Phosalone. (Unpublished study received Mar 26, 1971 under 1F1155; CDL:093475-C)
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OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.______________________ Date ______________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

EPA Form 8580-4

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________

Registrant's Name and Address: __________________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of "generic" data on the active ingredient _____________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated _________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ____________________ and their registration number(s) is/are ______________ .

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ________________________________
(Signature)

Dated: ________________ ________________________________
(Typed)

EPA Form 8570-27